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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,121	05/23/2006	David B. Smithrud	91830.0538278	2766

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EXAMINER	
STONE, CHRISTOPHER R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
12/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,121	SMITHRUD, DAVID B.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 28-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-27 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed August 5, 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Applicant's arguments with respect to claims 19-27 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

Claims 19, 20, 22, 24, 25 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al (US 6,242,430 B1).

Suzuki et al (US 6,242,430 B1) teaches a method comprising concurrently administering a host-rotaxane and an agent (a flourophore), wherein the host-rotaxane is a methylene chain, i.e. the host-rotaxane is not a polymer, in a pharmaceutically acceptable carrier, water, a liquid filler or diluent (Figures 2 and 3, column 1, lines 47-65 and column 10, lines 33-40). As for claim 22, Suzuki et al does not explicitly teach that the agent is administered to target cancers, tumors, etc.; however the instantly claimed active step of administering the rotaxane/agent complex to the instantly claimed patient population, a subject, is taught. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example,

the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir.1999). In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al (US 6,242,430 B1) in view of Nobuhiko (US 5,855,900).

Suzuki et al (US 6,242,430 B1) teaches a method comprising concurrently administering a host-rotaxane and an agent (a flourophore), wherein the host-rotaxane is a methylene chain, i.e. the host-rotaxane is not a polymer, in a pharmaceutically acceptable carrier, water (Figures 2 and 3, column 1, lines 47-65 and column 10, lines 33-40). Suzuki teaches that the agent is bound to a cyclodextrin guest molecule, which is associated with the host-rotaxane (Figures 2 and 3, column 1, lines 54-65). Suzuki et al further teaches the rotaxane complex is useful for medical diagnosis and treatment (column 10, lines 33-40 and column 11, lines 3-6). Suzuki et al does not explicitly teach

that the agent is a drug. Nobuhiko teaches that cyclodextrin guest molecules, associate with host rotaxanes, can be conjugated to a drug, providing controlled release of said drug (abstract, Figure 2). Therefore it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to modify the cyclodextrin of Suzuki et al with a desired drug to provide controlled release of said drug, since these host-rotaxane/guest molecule complexes were known to be useful in such application, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Claims 23, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al (US 6,242,430 B1) and Nobuhiko (US 5,855,900) as applied to claim 21 above, further in view of Goodman and Gilman's, The Pharmacological Basis of Therapeutics.

Suzuki et al and Nobuhiko teach the aforementioned host-rotaxane/guest molecule drug delivery complex, but fail to explicitly teach the routes of administration of claim 23, or the subsequent administration of an additional agent with bound or unbound to a guest molecule.

Goodman's and Gilman's teaches that it is common practice in the pharmaceutical art to select an appropriate route of administration (parenteral, oral, etc.) and carrier system (solid, aqueous solution, oily solution, etc.) to optimize bioavailability for a particular drug (Goodman and Gilman's, p. 5, right column through p. 6 left column, Table 1-1). Goodman's and Gilman's further teaches that the subsequent administration of the same drug or drugs may be desired to maintain a therapeutic

blood concentration of the drug or drugs over time (Goodman and Gilman's, p. 28 and p. 29, Maintenance Dose Heading).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to administer the composition via any conventional route of administration in conjunction with a conventional carrier system appropriate for said route (e.g. parenterally with a diluent or orally with an encapsulating material), since it is common practice in the pharmaceutical art to select an appropriate route of administration (parenteral, oral, etc.) and carrier system (solid, aqueous solution, oily solution, etc.) to optimize bioavailability for a particular drug (Goodman and Gilman's, p. 5, right column through p. 6 left column, Table 1-1). Additionally, the subsequent administration of an additional agent unbound or bound to a guest molecule (e.g. an unbound drug or the host-rotaxane/guest molecule drug delivery complex) would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention. The subsequent administration of the same drug or drugs may be desired to maintain a therapeutic blood concentration of the drug or drugs over time (Goodman and Gilman's, p. 28 and p. 29, Maintenance Dose Heading). Thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

01December2008
CRS

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645